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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/276,455      03/25/99      FERSHT

A      674508-2001

020999  
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NEW YORK NY 10151

HM12/0410

EXAMINER
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FIELDS, I	
ART UNIT	PAPER NUMBER

1645  
DATE MAILED:

04/10/01

17

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Applicati n No.

09/276,455

Applicant(s)

FERSHT ET AL.

Examiner

Ilesha P Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 2-8, 22-28, and 32-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9-21, and 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group I, claims 1, 9-21, and 29-31 (Paper Number 16) received on January 23, 2001 is acknowledged. The traversal is on the grounds that according to MPEP 803, if a search and examination can be made without serious burden, the Examiner must examine the claims on the merits, even though the claims include distinct or independent inventions. The argument that the restriction is improper because Group I (claims 1-21 and 29-31) and Group II (Claim 47) can be searched without serious burden is not found persuasive. It is the Examiner's position that it would be an undue burden to search all Groups as indicated by the divergent subject matter and different classification. In addition to different classifications of subject matter which is merely one indication of the burdensome nature of the search involved, each sequence in the case also requires a separate search of the prior art. It would be a serious burden on the examiner to search all groups because the above inventions are not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. For instance a search of the prior art to Group I drawn to a polypeptide would not reveal prior art of Group II drawn to a method of treatment as indicated by their different classification.

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Consequently, claims 1-50, and are pending in the instant application, and claims 2-8, 22-28, and 32-50 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

### **Drawings**

1. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 recites a chaperon polypeptide of a GroEL sequence substantially shown in Figure 7, or a corresponding sequence of a substantially homologous chaperon polypeptide, or a modified, mutated or variant sequence thereof having chaperon activity.

The specification and claim does not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the amino acid sequence shown in Figure 7 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

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3. Claims 1, 8-11, 14-21, and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The claims are vague and indefinite in the recitation of a GroEL "substantially" as shown in Figure 7. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance what constitutes the term substantially, 90%, 95% or 99% etc. Without a clear definition as to what constitutes substantially, one of skill in the art would be unable to replicate the claims.

B) The claims are further vague and indefinite in the recitation of a "substantially homologous" chaperone polypeptide. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance what level of homology, 50%, 75%, 99% etc. does the applicant intend? Without a clear definition as to what constitutes "substantially homologous" one of skill in the art would be unable to replicate the claim.

C) The claims are further vague and indefinite in the recitation of a "modified, mutated or variant" sequence thereof. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, would one amino acid substitution constitute a "modified, mutated or variant" sequence? Without a clear

definition as to what constitutes a modified, mutated or variant sequence one of skill in the art would be unable to replicate the claim.

D) Claim 8 is vague and indefinite in the recitation of "preferably" and "even more preferably". One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, what level of protein folding activity does the applicant intend 65%, 75%, 95% etc? Without a clear definition as to the "preferred" level of protein folding activity one of skill in the art would be unable to replicate the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, and 9-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Braig et al.

The claims are drawn to GroEL polypeptides.

Braig et al. (Nature 1994 Vol. 371 (6498) pp.578-86) disclose the entire amino acid sequence of *E. coli* GroEL. Because the chaperone polypeptides claimed by the

applicant are inherent to the entire amino acid sequence of which is *E. coli* GroEL disclosed by Braig et al. the prior art anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 18-21 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braig et al. in view of Holland et al.



The claims are drawn to a recombinant *E. coli* GroEL fusion polypeptide.

The teachings of Braig et al. are set forth above.

Braig et al. does not teach of a recombinant *E. coli* GroEL fusion polypeptide.

Holland et al. (US Patent 5,143,830) teach of a process of making recombinant fusion polypeptides including polypeptides of bacterial origin (See Summary of the Invention). Holland et al. further teach of immobilization of a polypeptide to an agarose resin (See Material and Methods Section).

Given that 1) Braig et al. has taught of the entire amino acid sequence of *E. coli* GroEL and that 2) Holland et al. has taught of a process of making a recombinant fusion polypeptide it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a recombinant *E. coli* GroEL fusion polypeptide and use the polypeptide as a diagnostic tool in the treatment of disease. One would have been motivated to make a recombinant *E. coli* GroEL fusion polypeptide in view of the teachings of Holland et al. that such polypeptides may be useful in diagnostic assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

April 9, 2001



MARK NAVARRO  
PRIMARY EXAMINER